

REMARKS

Claims 1, 2, 5, and 6 are pending in the application.

The Drawings filed are objected to by the Examiner

Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 112, second paragraph.

Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 112, first paragraph. Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quackenbush (Nature Reviews Genetics, June 2001, Vol. 2 P. 418-427), in view of GRAPHING WITH LOGARITHMIC PAPER (Department of Physics, University of Guelph, <http://www.physics.uoguelph.ca/tutorials/GLP>, Published Oct. 1997, P. 1-5)

Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US Pat. No. 6,571,005; Filed Apr. 21, 2000), in view of Stark et al. (US 5,568,400; Issued Oct. 22, 1996) and GRAPHING WITH LOGARITHMIC PAPER (Department of Physics, University of Guelph, <http://www.physics.uoguelph.ca/tutorials/GLP>, Published Oct. 1997, P. 1-5).

The Applicants traverse the rejections and request reconsideration.

Drawings

The Drawings filed are objected to by the Examiner for various informalities. The Examiner is believed to be unreasonable in making this objection. Paragraph [0027] of the published Application clearly notes that the horizontal axis 1 represents the logarithm of the gene expression quantities obtained for the first sample and that horizontal axis 2 represents the logarithm of the of the gene expression quantities for the second sample. The present invention is not restricted to any specific type of gene expression data, but covers all types of gene

expression data. The Applicants respectfully submit all the requirements for drawings as explained in MPEP § 608.02(d) have been satisfied.

Claim Rejections Under 35 U.S.C. § 112, 2nd paragraph and new matter rejection

The Examiner is believed to be unreasonable in making the section 112 indefiniteness rejection and the new matter rejection. In fact, the arguments made by the Examiner are believed to be internally inconsistent

The Applicants respectfully added the phrase “x and y” to the claims to provide clarification. The Examiner now finds that this is unsupported by the Specification. “[T]he ‘essential goal’ of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.” *In re Barker*, 559 F.2d 588, 592 n.4, (CCPA 1977). In essence, the “written description” requirement requires that each and every element in the claims be adequately described in the Specification to show one of skill in the art that the inventor was in possession of the invention at the time the application was filed. *See Manual Of Patent Examining Procedure (“MPEP”) § 2163.02.* Further, “all that is necessary to satisfy the description requirement is to show that one is ‘in possession’ of the invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1999).

However, it is well settled that “[i]t is not necessary that the claimed subject matter **be described identically**, but the disclosure originally filed must convey to those skilled in the art that the applicant has invented the subject matter claimed.” *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984) (citation omitted). Indeed, “[i]n order to satisfy the written description requirement, the disclosure as originally filed **does not have to provide in haec verba support**

for the claimed subject matter at issue.” *Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1376 (Fed. Cir. 2002); See *In re Werthheim*, 541 F.2d 257, 265 (CCPA 1976) (“Lack of literal support...is not enough...to support a rejection under § 112.”).

It is clear that the gene expression data is represented in axes “x and y.” In fact, in making the section 112, second paragraph, rejection, the Examiner takes a position that “data is typically represented on coordinate systems using x-axis (horizontal) and y-axis (vertical).” Therefore, the Examiner appears to be taking a position that it is not well-known that data is shown in x and y axes in making the new matter rejection and taking a completely contrary position in making the section 112, second paragraph rejection.

In addition, the Applicants respectfully amend the claims to further clarify the subject matter of the invention.

Claim Rejections Under 35 U.S.C. 103

Rejection of claims 1, 2, 5 and 6 under 35 U.S.C. 103(a) as being unpatentable over Quackenbush (Nature Reviews Genetics, June 2001, Vol. 2 P. 418-427), in view of GRAPHING WITH LOGARITHMIC PAPER

While the Examiner admits that the cited references do not specifically discuss finds the determination of coefficient 10^8 and using it to normalize data as in the present invention. The Examiner unreasonably takes a position that the type of normalization used would have been obvious to a skilled artisan. The Applicants respectfully disagree.

The Applicants respectfully submit that the specific type of normalization that is performed as in the present invention is not predictable. As the Examiner very well know, the concept of normalization itself is well known. However, there are infinite number of ways to perform normalization, each with widely varying results. A skilled artisan would not have been able to predict the specific way of normalization as used in this invention. A skilled artisan

would not have been able to predict obtaining the coefficient 10^a after obtaining an approximate representation of the plotted points with a straight line $\log y = \log x + a$, with a slope 1. Further, a skilled artisan would not have been able to predict dividing the data for the second sample by the coefficient 10^{-a} .

Further, the standard for determining obviousness should focus on “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *KSR International Co. v. Teleflex Inc.*, 127, S.Ct. 1727 (2007). Further, when there is a design need or *market pressure* to solve a problem and there are *a finite number of identified, predictable solutions*, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the *anticipated success*, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103. *Forest v. Ivax* (CAFC Sept. 5, 2007) *citing KSR*.

As can be noted in the *Forest* case a skilled artisan would have a good reason to pursue options that are known when there a finite number of identified, predictable solutions. However as any skilled person working with data normalization knows, there are literally an infinite numbers of ways of normalizing data. There is no reason to believe that a skilled artisan would have chosen this specific claimed way of plotting the data on logarithmic graph, determining the value of the coefficient 10^a , normalizing the data by dividing the data for the second sample by this coefficient.

Therefore, the obviousness rejection of the claims based on Quackenbush must be withdrawn.

Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li, Stark et al and GRAPHING WITH LOGARITHMIC PAPER

The Applicants respectfully submit that the Examiner has relied on Quackenbush for alleged suggestions related to the data normalization. The above discussion clearly identifies the deficiencies noted in the teachings of Quackenbush. Li and Stark do not overcome the above-noted deficiencies in the teachings of Quackenbush.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Chidambaram. S. Iyer/

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

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CUSTOMER NUMBER

Chid S. Iyer
Registration No. 43,355

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